



FH

**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/149039

PRELIMINARY RECITALS

Pursuant to a petition filed April 26, 2013, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on June 05, 2013, at Racine, Wisconsin.

The issue for determination is whether a prior authorization request for Wisconsin Medicaid program payment for a prescription drug meets the standards necessary for Medicaid payment for that drug.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street
Madison, Wisconsin 53703

By: Lynn Radmer, R.Ph.

Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

David D. Fleming
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Racine County.

2. A prior authorization request seeking Medicaid payments for a prescription drugs, Cayston, was filed on behalf of Petitioner on or about January 16, 2013.
3. Cayston is an inhaled antibiotic used to improve respiratory symptoms in people with cystic fibrosis who have a specific bacterial infection in their lungs, *Pseudomonas aeruginosa*.
4. At the time of this PA request the inhaled antibiotic class of drugs contained only two drugs TOBI and Cayston. TOBI is available without prior authorization. Cayston requires prior authorization. Based on studies and FDA recommendations, clinical criteria for approval of Medicaid payment for a treatment regimen of Cayston requires 28 days of treatment followed by 28 days without inhaled antibiotic therapy. The cycle can then be repeated.
5. This prior authorization request was denied. The denial is detailed in a lengthy letter from the Division of Health Care Access and Accountability dated May 29, 2013.

DISCUSSION

All prior authorization requests must meet the following a prior authorization review criteria listed at *Wis. Admin. Code, §DHS 107.02(3)(e)*:

(e) *Departmental review criteria.* In determining whether to approve or disapprove a request for prior authorization, the department shall consider:

1. The medical necessity of the service;
2. The appropriateness of the service;
3. The cost of the service;
4. The frequency of furnishing the service;
5. The quality and timeliness of the service;
6. The extent to which less expensive alternative services are available;
7. The effective and appropriate use of available services;
8. The misutilization practices of providers and recipients;
9. The limitations imposed by pertinent federal or state statutes, rules, regulations or interpretations, including medicare, or private insurance guidelines;
10. The need to ensure that there is closer professional scrutiny for care which is of unacceptable quality;
11. The flagrant or continuing disregard of established state and federal policies, standards, fees or procedures; and
12. The professional acceptability of unproven or experimental care, as determined by consultants to the department.

“Medically necessary” means a medical assistance service under ch. DHS 107 that is:

(a) Required to prevent, identify or treat a recipient's illness, injury or disability; and

(b) Meets the following standards:

1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
3. Is appropriate with regard to generally accepted standards of medical practice;
4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;
6. Is not duplicative with respect to other services being provided to the recipient;
7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and

9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.

Wis. Admin. Code, §DHS 101.03(96m).

As with most public assistance benefits the initial burden of demonstrating eligibility for any particular benefit or program at the operational stage falls on the applicant, *Gonwa v. Department of Health and Family Services*, 2003 WI App 152, 265 Wis.2d 913, 668 N.W.2d 122 (Ct.App.2003). In other words, it is a Petitioner's burden to demonstrate that s/he qualified for the requested continued services by a preponderance of the evidence. It is not the Department's burden to prove that s/he is not eligible.

Further, I note that Medicaid is meant to provide the most basic and necessary health care services at a reasonable cost to a large number of persons and must authorize services according to the Wisconsin Administrative Code definition of medical necessity and other review criteria noted above. It is not enough to demonstrate a benefit; rather, all of the tests cited above must be met.

Additionally, there are specific approval criteria specific to particular medical services. For Cayston the following is required:

As a reminder, clinical criteria for approval of a PA request for Cayston are the following:

- The member has a diagnosis of cystic fibrosis.
- The prescriber has confirmed the member currently has a positive sputum culture for *Pseudomonas aeruginosa* or the member had a positive sputum culture for *Pseudomonas aeruginosa* within the past 12 months. Providers should indicate the date of the positive sputum culture.
- The prescriber has confirmed the member currently does not have *Burkholderia cepacia* colonized in the lungs.
- The member is 7 years of age or older.
- The member has previously used Tobi and experienced a clinically significant adverse drug reaction or an unsatisfactory therapeutic response. Providers should indicate the specific details about the clinically significant adverse drug reaction or the unsatisfactory therapeutic response and the approximate dates Tobi was taken on the PA request.
- The prescriber has confirmed the member's FEV1 percent [forced expiratory volume over one second] predicted is greater than or equal to 25 percent and less than or equal to 75 percent. Providers should indicate the member's current FEV1 percent predicted on the PA request.
- The member is not receiving treatment with other inhaled/nebulized antibiotics or inhaled/nebulized anti-infective agents, including alternating treatment schedules. Providers should provide a history of all inhaled/nebulized antibiotics or inhaled/nebulized anti-infective agents and a history of all systemic antibiotics/anti-infective agents within the most recent 90-day period.

ForwardHealth Update September 2010, No. 2010-84, pages 2-3.

Available online at <https://www.forwardhealth.wi.gov/kw/pdf/2010-84.pdf>

The Department denied the request because Petitioner's FEV1 is in excess of 75% and because the request seemed indicate that Petitioner was being treated on a continuous basis with Cayston.

I am sustaining the department denial of this PA. The evidence is not demonstrate that the approval criteria outlined above are met; in particular, the requirement that the FEV1 be greater than 25% but less than 75%.

CONCLUSIONS OF LAW

The evidence does not demonstrate that this prior authorization request meets the criteria necessary for payment by the Wisconsin Medicaid program.

THEREFORE, it is

ORDERED

That this appeal is dismissed.

REQUEST FOR A REHEARING

This is a final administrative decision. If you think this decision is based on a serious mistake in the facts or the law, you may request a rehearing. You may also ask for a rehearing if you have found new evidence which would change the decision. Your request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and tell why you did not have it at your first hearing. If you do not explain these things, your request will have to be denied.

To ask for a rehearing, send a written request to the Division of Hearings and Appeals, P.O. Box 7875, Madison, WI 53707-7875. Send a copy of your request to the other people named in this decision as "PARTIES IN INTEREST." Your request for a rehearing must be received no later than 20 days after the date of the decision. Late requests cannot be granted.

The process for asking for a rehearing is in Wis. Stat. § 227.49. A copy of the statutes can be found at your local library or courthouse.

APPEAL TO COURT

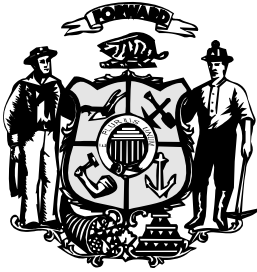
You may also appeal this decision to Circuit Court in the county where you live. Appeals must be served and filed with the appropriate court no more than 30 days after the date of this hearing decision (or 30 days after a denial of rehearing, if you ask for one).

For purposes of appeal to circuit court, the Respondent in this matter is the Department of Health Services. After filing the appeal with the appropriate court, it must be served on the Secretary of that Department, either personally or by certified mail. The address of the Department is: 1 West Wilson Street, Madison, Wisconsin 53703. A copy should also be sent to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400.

The appeal must also be served on the other "PARTIES IN INTEREST" named in this decision. The process for appeals to the Circuit Court is in Wis. Stat. §§ 227.52 and 227.53.

Given under my hand at the City of Milwaukee,
Wisconsin, this 12th day of July, 2013

\sDavid D. Fleming
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on July 12, 2013.

Division of Health Care Access And Accountability